IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Romeo et al.	Examiner:	Ketter, J.S.
Serial No.:	10/826,967	Group Art Unit:	1636
Filed:	April 16, 2004	Docket No.:	14233.4USU1
Customer No.	23552	Confirmation No.	2920
Title:	NOVEL GENES INVOLVED IN THE *ESCHERICHIA COLI* BIOFILM FORMATION AND USES THEREOF		

RESPONSE TO RESTRICTION REQUIRMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Restriction Requirement of July 28, 2006, the date for timely reply being extended 1-month from August 28, 2006 to September 28, 2006, Applicants timely submit the following Response.

The Examiner has restricted the claims of the above-identified application to one of the 61 different recited genes. The Examiner asserts that each gene is distinct since each separate gene encodes a patentably distinct gene product having a discrete function, and thus a different mode of operation.

Without acquiescing to the statements made in the Restriction Requirement, Applicants hereby elect with traverse the gene *nhaR* for prosecution in the instant application.

Under MPEP § 803, there are two requirements for restriction. First, the Examiner must show that the related inventions are independent or patentably distinct as claimed. Second, the Examiner must explain why there would be a serious burden if restriction is not required. The MPEP guidelines indicate that the Examiner must provide reasons and/or examples to support one of the following:

(a) Separate classification thereof: this shows that each invention has attained recognition in the art as a separate subject for invented effort, and also a separate field of search. Patents need not be cited to show separate classification;

(b) A separate status in the art when they are classifiable together: even though they are classified together, each invention can be shown to have formed a separate subject for inventive effort when the Examiner can show a recognition of separate inventive effort by inventors. Separate status in the art may be shown by citing patents which are evidence of such separate status, and also of a separate field of search; or

(c) A different field of search: where it is necessary to search for one of the inventions in a manner that is not likely to result in finding art pertinent to the other inventions, (e.g. different searching, different classes/ subclasses or electronic resources, or employing different search queries) a different field of search is shown, even though the two are classified together. The indicated different field of search must in fact be pertinent to this type of subject matter covered by the claims. Patents need not be cited to show different fields of search.

However, where the classification is the same and the field of search is the same and there is no clear indication of separate future classification and field of search, no reasons exist for dividing and it is improper to divide among related inventions.

Applicants respectfully submit that the Examiner has not met either of the two requirements for showing the search would by unduly burdensome. In fact, the Examiner has not even addressed undue burden in the Examiner's report. As such, Applicants respectfully assert that the restriction requirement is improper. Since the Examiner has not established reasons for restriction or an undue burden for searching, Applicants are unable to specifically refute.

The Examiner's restriction requirement appears to be based on the assumption that each separate gene encodes a patentably distinct gene product *having a discrete function and mode of operation*. The onus is on the Examiner to show that each of these gene products has a discrete function and a discrete mode of operation. Several of these genes and gene products have very similar functions and modes of operation. Specifically, the following genes are part of the *LysR* family of transcriptional regulator of pgaABCD (the operon required for production of the

biofilm adhesion in PGA): *nhaR, leuO, yjjQ, yhjH, arcB, yedK, modA, miaA, yojN*, and *b1936.* For example, *nhaA* is regulated by *nhaR*, part of the LysR family of transcriptional regulators. Also included is *leuO* , a LysR-like regulator. These genes have similar functions and related modes of operation, namely regulating transcription of this operon. If the Examiner were to restrict the claims based on similar functions, Applicants would elect a restriction Group of the following 10 sequences*:* *nhaR*, *leuO*, *yjjQ*, *yhjH*, *arcB*, *modA*, *yojN*, *b1936*, *b1904*, and *yhdA*.

In addition, MPEP § 803.04 specifically allows for multiple nucleotide sequences in one application without restriction. Specifically, § 803.04 states:

> "Polynucleotide molecules defined by their nucleic acid sequence (hereinafter "nucleotide sequences") that encode different proteins are structurally distinct compounds. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C.121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Nevertheless, to further aid the biotechnology industry in protecting its intellectual property without creating an undue burden on the Office, the Director has decided *sua sponte* to partially waive the requirements of 37 CFR 1.141 et seq. and permit a reasonable number of such nucleotide sequences to be claimed in a single application… It has been determined that normally ten sequences constitute a reasonable number for examination purposes… In addition to the specifically selected sequences, those sequences which are patentably indistinct from the selected sequences will also be examined. Furthermore, nucleotide sequences encoding the same protein are not considered to be independent and distinct inventions and will continue to be examined together.

Applicants respectfully submit that the purported 61 different inventions should be examined in one application. Applicants respectfully submit that the Examiner has not met the above requirements for showing that restriction is required. Additionally, the Examiner has not provided a valid reason for why a search including more than one of Groups 1 to 61 would be

unduly burdensome. Applicants respectfully assert that the Examiner has not met the burden to show why restriction is necessary.

Applicants submit that the claims of the present application are in condition for allowance and notification to that effect is earnestly solicited. The Examiner is invited to contact Applicant's representative at the telephone number listed below, if the Examiner believes that doing so will advance prosecution.

Respectfully submitted,

MERCHANT & GOULD P.C.
P.O. Box 2903
Minneapolis, Minnesota 55402-0903
(612) 332-5300

Date: September 28, 2006

Brian R. Dorn, Ph.D.
Reg. No. 57,395
BRD:RAD:lek